

## **Chemotherapy Protocol**

#### **ACUTE MYELOID LEUKAEMIA**

# CYTARABINE (1500mg/m<sup>2</sup>)

## **In-Patient Regimen**

# Regimen

Acute Myeloid Leukaemia – InP-Cytarabine (1500mg/m²)

## Indication

- Consolidation for good risk acute myeloid leukaemia following induction chemotherapy.
- Relapsed disease post transplant.
- The standard dose is 3000mg/m<sup>2</sup>. The dose may be decreased to 1500mg/m<sup>2</sup> in those who are elderly on in those who have relapsed post transplant where the 3000mg/m<sup>2</sup> dose may not be tolerated.

## **Toxicity**

| Drug       | Adverse Effect  |
|------------|---|
| Cytarabine | Nausea, vomiting, diarrhoea, fever, rash, itching, anorexia, oral and anal inflammation or ulceration, hepatic dysfunction, ocular pain, foreign body sensation, photophobia and blurred vision, dizziness, headache, confusion, cerebellar toxicity, myalgia and bone pain |

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

### Monitoring

#### Drugs

• U&Es, LFTs and FBC prior to starting a cycle of treatment

# **Dose Modifications**

The dose modifications listed are for haematological, liver and renal function and drug specific toxicities only. Dose adjustments may be necessary for other toxicities as well.

In principle all dose reductions due to adverse drug reactions should not be re-escalated in subsequent cycles without consultant approval. It is also a general rule for chemotherapy that if a third dose reduction is necessary treatment should be stopped.



### Haematological

In general the treatment can proceed if the neutrophils are greater than  $1x10^9/L$  and the platelets are greater than  $100x10^9/L$ . Always' check with the relevant consultant.

Consider blood transfusion if the patient symptomatic of anaemia or has a haemoglobin of less than 8g/dL (80g/L).

## Hepatic Impairment

| Drug       | Bilirubin       | AST/ALT | Dose   |
|------------|-----------------|---------|--|
|            | µmol/L          | units/L | (% of original dose)   |
| Cytarabine | greater than 34 | N/A     | 50% Escalate doses in subsequent cycles in the absence of toxicity |

### Renal Impairment

| Drug       | Creatinine Clearance (ml/min) | Dose<br>(% of original dose) |
|------------|-------------------------------|------------------------------|
|            | less than 60                  | 60%                          |
| Cytarabine | less than 45                  | 50%                          |
|            | less than 30                  | Discuss with consultant      |

#### Other

Dose reductions or interruptions in therapy are not necessary for those toxicities that are considered unlikely to be serious or life threatening. For example, alopecia, altered taste or nail changes.

### Regimen

1 - 2 cycles (1 cycle will be set in ARIA)

Cycle two, if required, should proceed when there is neutrophil and platelet recovery and the response to cycle one has been assessed.

| Drug       | Dose                                 | Days    | Administration  |
|------------|--------------------------------------|---------|---|
| Cytarabine | 1500mg/m <sup>2</sup><br>twice a day | 1, 3, 5 | Intravenous infusion in 1000ml sodium chloride 0.9% over 240minutes |

### **Dose Information**

- Cytarabine will be dose banded according to the national dose bands (100mg/ml)
- The daily doses should be given 12 hours apart
- The standard dose is 3000mg/m<sup>2</sup>. The dose may be decreased in those who are elderly on in those who have relapsed post transplant where the 3000mg/m<sup>2</sup> dose may not be tolerated.



### **Administration Information**

#### Extravasation

Cytarabine – neutral (irritant in large volumes)

### Other

The daily doses of cytarabine should be given 12 hours apart

### **Additional Therapy**

This is an inpatient regimen please ensure all supportive are prescribed on the inpatient chart or general electronic prescribing system.

Antiemetics

Starting 15 - 30 minutes prior to chemotherapy

- metoclopramide 10mg three times a day when required oral
- ondansetron 8mg twice a day on days 1, 2, 3, 4, 5 oral
- Aciclovir 400mg twice a day until neutrophils are greater than 1x10<sup>9</sup>/L
- Discuss the need and choice of antifungal with a consultant
- Prednisolone eye drops 0.5% into each eye four times a day. Continue for 5 days after cytarabine administration
- Allopurinol 300mg daily for first 7 days of initial induction chemotherapy. This is not generally required where the cytarabine is being prescribed in the consolidation setting
- Mouthwashes according to local or national policy on the treatment of mucositis
- Gastric protection with a proton pump inhibitor or a H<sub>2</sub> antagonist may be considered in patients considered at high risk of GI ulceration or bleed.

## Coding

- Procurement X71.5
- Delivery NA

## References

1.Lowenberg B. Sense and nonsense of high dose cytarabine for acute myeloid leukemia. Blood 2013: 121: 26-28.



#### **REGIMEN SUMMARY**

InP-Cytarabine (1500mg/m<sup>2</sup>)

Other than those listed below, supportive medication for this regimen will not appear in Aria as prescribed agents. The administration instructions for each warning describes the agents which must be prescribed on the in-patient chart or general electronic prescribing system

## Day 1, 3, 5

1. Warning – Check supportive medicines prescribed

Administration Instructions

- ondansetron 8mg twice a day oral or intravenous for 7 days
- metoclopramide 10mg three times a day when required for nausea oral or intravenous
- aciclovir 400mg twice a day oral
- discuss the need and choice of antifungal with a consultant
- consider allopurinol 300mg once a day for 7 days oral (review cycle 2 or if consolidation treatment)
- prednisolone 0.5% eye drops, 1 drop each eye four times a day. Continue for 5 days after cytarabine administration is complete

Always refer to the patient schedule for supportive treatments and fluids

2. Warning – Cytarabine is TWICE a day

Administration Instructions

The daily doses of cytarabine should be given 12 hours apart

3. Cytarabine 1500mg/m² twice a day in 1000ml sodium chloride 0.9% intravenous infusion over 240minutes twice a day 12 hours apart

Administration Instructions

The daily doses of cytarabine should be given 12 hours apart



## **DOCUMENT CONTROL**

| , | Version | Date          | Amendment    | Written By                      | Approved By  |
|---|---------|---------------|--------------|---------------------------------|--|
|   | 1       | March<br>2017 | New protocol | Dr Deborah Wright<br>Pharmacist | Dr Deborah Richardson<br>Consultant<br>Haematologist |

This chemotherapy protocol has been developed as part of the chemotherapy electronic prescribing project. This was and remains a collaborative project that originated from the former CSCCN. These documents have been approved on behalf of the following Trusts;

Hampshire Hospitals NHS Foundation Trust NHS Isle of Wight Portsmouth Hospitals NHS Trust Salisbury Hospitals NHS Foundation Trust University Hospital Southampton NHS Foundation Trust Western Sussex Hospitals NHS Foundation Trust

All actions have been taken to ensure these protocols are correct. However, no responsibility can be taken for errors that occur as a result of following these guidelines.